91-1018

No.

IN THE

Supreme Court of the United States

OCTOBER TERM, 1991

THE NORTHERN TRUST COMPANY,
Successor Guardian of the Estate
of SHELBY ANDERSON MORAN, a Disabled Person,

Petitioner,

v.

THE UPJOHN COMPANY, JOHN J. BARTON, M.D.,
and ILLINOIS MASONIC MEDICAL CENTER,

Respondents.

Petition For Writ Of Certiorari To The Appellate Court Of Illinois, First Judicial District

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED FOR REVIEW

I. Where:

(1) 21 U.S.C., §352 mandates warnings in drug labeling and directs the Commissioner of the Food and Drug Administration (FDA) to promulgate regulations thereunder; and

(2) In promulgating his regulations, the FDA Commissioner specifically rejected proposals that "experts" should decide the adequacy of the warning and that expert or academic debate as to causation be taken into account when determining a manufacturer's affirmative duty to warn, and

(3) Instead, promulgated regulations setting forth "bright line" standards requiring manufacturers to warn of any reported adverse reactions associated with the use of the drug,

Can a State court reject the federal law and, on the contrary, eviscerate its absolute standards by permitting the adequacy of drug labeling to be redetermined by experts engaged by the manufacturer specifically for that sole purpose?

II. Have this plaintiff's due process rights protected under the Fourteenth Amendment of the Constitution been violated when:

(1) The Constitution of Illinois affirmatively guarantees the right to trial by jury (Article I, §13, 1970 Constitution), and

(2) The plaintiff has taken those procedural steps to secure that right, resulting in a jury's verdict in her favor, and

(3) The Appellate Court, to reverse that judgment, creates new evidentiary burdens as a matter of first impression, selectively reweighs and excludes evidence based upon those new evidentiary burdens, and reverses that judgment without remand, denying the plaintiff an opportunity to meet those burdens on retrial?

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REFERENCE TO THE OFFICIAL REPORT OF OPINION

The opinion is reported at 213 Ill.App.3d 390, 157 Ill. Dec. 566, 572 N.E.2d 1030 (1991).

JURISDICTION

Jurisdiction is invoked pursuant to Title 28 U.S.C. §1257(a). The opinion of the Appellate Court of Illinois, First District, was filed April 26, 1991 (Doc. 1-89-2165, 2244, 2357 Cons.); a petition for leave to appeal to the Supreme Court of Illinois from that ruling was filed shortly thereafter, and that petition for leave to appeal was denied on October 2, 1991 (Docket 71892). A motion was filed to reconsider the denial of the petition for rehearing; that motion was denied on November 4, 1991.

In particular, plaintiff predicated its theory of liability of defendant Upjohn Company upon the federal statutes and the regulations of the FDA Commissioner requiring warnings with respect to drugs, which regulations were not complied with by the said defendant. A judgment was entered upon the verdict of a jury for plaintiff and against defendant in the amount of $9,510,301.00.

However, the Appellate Court of Illinois, 213 Ill.App.3d 390, 572 N.E.2d 1030, 157 Ill.Dec. 566 reversed this judgment on a ground contrary to federal law; namely, that "expert" evidence rather than FDA regulations governed the adequacy of labeling and it violated plaintiff's ward's due process right that secures to her the right to trial by jury. The issues were raised in plaintiff's petition for leave to appeal to the Illinois Supreme Court, denied by that court.

CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED IN THE CASE

CONSTITUTIONAL PROVISIONS

AMENDMENT XIV

Section 1. . . . nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

AMENDMENT VII

In suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any Court of the United States, than according to the rules of the common law.

CONSTITUTION OF THE STATE OF ILLINOIS 1970

Article I, §13. Trial by Jury

The right of trial by jury as heretofore enjoyed shall remain inviolate.

FEDERAL STATUTE

21 U.S.C. §352, (a), (f), (j), (n):

Misbranded drugs and devices

A drug or device shall be deemed to be misbranded—

False and misleading label

(a) If its labeling is false or misleading in any particular.

Directions for use and warnings on label

(f) Unless its labeling bears (1) adequate directions for use, and (2) such adequate warnings against use in those

pathological conditions . . . where its use may be dangerous to health . . .

Health-endangering when used as prescribed

(j) If it is dangerous to health when used in the dosage . . . recommended, or suggested in the labeling thereof.

Prescription drug advertisements; established name; quantitative formula; side effects, contraindications, and effectiveness; prior approval; false advertising; labeling

(n) In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all . . . descriptive printed matter issued or caused to be issued by the manufacturer, . . . such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations . . .

FEDERAL REGULATIONS

21 C.F.R. 1.3(a)(1)(2); 314.8(a)(b)(d)(e)(*l*):

Labeling of a food, drug, device, or cosmetic shall be deemed to be misleading if it fails to reveal facts that are: (1) material in light of other representations made or suggested by statement, word, design, device or any combination thereof; or (2) material with respect to consequences which may result from use of the article under (i) the conditions prescribed in such labeling or (ii) such conditions of use as are customary or usual.

* * *

(d) The changes of the following kinds proposed in Supplemental New Drug Applications should be placed into effect at the earliest possible time:

(1) The addition to package labeling, promotional labeling, and prescription drug advertising of an additional warning, contraindication, side-effect, and precaution information.

* * *

(e) It will be the policy of the Food and Drug Administration to take no action against a drug applicant solely because changes of the kind described in paragraph (d) of this section are placed in effect by the applicant prior to his receipt of a written notice of approval of the Supplemental New Drug Application . . .

STATEMENT OF THE CASE

Petitioner's ward, Shelby Moran, sustained brain damage during a second trimester abortion performed at Illinois Masonic Medical Center in 1978; the abortifacient was Prostaglandin F_2 Alpha (PGF_2 Alpha), manufactured and marketed by the defendant The Upjohn Company for induction of 2nd trimester abortions. The manufacture and marketing of that drug was strictly regulated by federal law; further, the Commissioner of the Food and Drug Administration was empowered by Congress to make regulations to enforce that federal law. At trial, the jury was asked to decide whether or not Upjohn's product was defective because of its failure to include in its labeling the occurrence of cardiac arrest and death associated with use of the drug; the jury was instructed with the language of the federal statute requiring warnings of adverse reactions. Expert testimony addressed the causal connection between the use of the drug and Shelby Moran's cardiac arrest, the conduct of the defendant hospital, its personnel, and the defendant physician. The jury returned a verdict in favor of the plaintiff and against all of the defendants in the amount of $9,510,301.00.

The appellate court of Illinois reversed the judgment, without remanding for a new trial. The court's opinion identified three issues of first impression (Appendix pp. 7a, 12a-13a, 20a), including whether an expert witness was required to interpret the language of the federal act and accompanying regulations, despite the availability of the written interpretation of the Commissioner of the Bureau of Drugs on the very issue presented for disposition.

In an additional issue of first impression, the court imposed new standards by which the competency of expert witnesses should be measured. The appellate court did not remand the case to give plaintiff an opportunity either to acquire the expert testimony allegedly required to interpret federal law, or to meet the new competency standards for expert witnesses on unrelated issues.

The appellate court's holding and disposition of this case first created the federal question and the constitutional issues. In petitioner's petition for leave to appeal to the Supreme Court of Illinois those issues were raised at the first opportunity. That petition was timely filed and then denied on October 2, 1991. After the denial of the petition for leave to appeal on October 2, 1991, plaintiff filed a motion for leave to file a motion for reconsideration, which was denied on November 4, 1991.

The federal question and violation of constitutional right(s) were set forth in the petition for leave to appeal and is set forth in part I(a.)(b.) at page 3 and in II(b.)(i). The issues were argued in the petition for leave to appeal under part V, pages 26-29, pages 58-67. (See Appendix, pp. 26a-40a).

ARGUMENT

I.

THE QUESTION HERE IS IMPORTANT AND SHOULD BE DECIDED BY THIS COURT.

This case presents an important federal question. The holding of the appellate court repudiates both the language and spirit of the laws which tightly regulate the manufacture and sale of ethical drugs. The holding delegates the interpretation of the labeling provisions of federal law to debate by "experts," a concept previously urged on the Commissioner of Food and Drugs, and specifically rejected. The opportunity afforded to hired experts to interpret and debate and dilute labeling requirements will insulate the drug industry from the present mandatory labeling requirements if those partisan experts, and not the federal authorities vested with that power, interpret and decide the content of warning labels.

This case arises from the marketing of an ethical drug found by the jury that heard the evidence to be misbranded, and therefore unreasonably dangerous and negligently manufactured. Evidence established that Upjohn knew that cardiac arrest and death were potential hazards of the drug's use, but did not warn doctors accordingly. Plaintiff relied upon the breach of federal law and regulations to establish the product was unreasonably dangerous and to establish Upjohn's duty to warn physicians and health care providers about the risk of cardiac arrest and death associated with the use of Prostaglandin F_2 Alpha and its failure to meet that duty. (Title 21 U.S.C. Sec. 352(a), (f), (j), (n); 21 C.F.R. Secs. 1.3(a)(1), (2); 314.8(a), (b), (d), (e), (*l*).).

The interpretation of the Food and Drug Act by the Food and Drug Administration (FDA) has been held by this court to be sufficiently rational to preclude a court from substituting its judgment for that of the FDA. *Young v. Community Nutrition Institute*, 476 U.S. 974 (1986). Federal and state courts in the past have held that a breach of a statutory duty establishes *prima facie* evidence of negligence and in products cases alleging a failure to warn breach of a statutory duty establishes an unreasonably dangerous product. *Stanton v. Astra Pharmaceutical Products*, 718 F.2d 553 (CA 3rd 1983). The interpretation of those regulations by the Commissioner have been held to have the force of law. *Pharmaceutical Mfrs. v. Food & Drug Adm.*, 484 F.Supp. 1179 (USDC Del. 1980), affirmed 634 F.2d 106.

In stark contrast to the result in the Illinois court, the Commissioner of the Food and Drugs, charged with regulating drug labeling, has interpreted the federal regulatory scheme regarding labeling, 39 FR 33232 (September 16, 1974):

> "An adequate warning of possible danger must appear in all such labeling. Without such a warning, a product is misbranded. The statute presupposes a difference of medical opinion since the danger need not be established and absolute, but rather merely potential. . . . Where potential danger is the statutory standard, a warning must be encumbered and unambiguous."

The Commissioner again commented at 40 FR 28582 (July 7, 1975), about misbranding,

> "The act provides that a . . . drug, . . . is misbranded if its labeling is false or misleading in any particular. *The courts have uniformly held that a single misleading representation is sufficient to render a product misbranded.* . . . The courts have

> also recognized that partial or half truths may render labeling misleading in violation of the act. . . . (emphasis added)

At 28583:

> . . . The statute requires that a warning be placed on the label when there is a potential hazard, as well as when there is proof of a causal relationship between the hazard and the drug. The congressional requirement of a clear drug warning under these circumstances assures that a potential hazard will be brought the to the attention of physicians in straightforward and concise terms."

The Commissioner reinforced the same principle in 1979, 44 FR 37447-37448:

> "The statutory scheme for drug labeling requires that potential hazards as well as known hazards, be included in labeling."

The conduct of John Barton, plaintiff's treating physician, underscores the risk of incomplete or misleading warnings; he testified that had he been warned of the risk of cardiac arrest with Prostaglandin F_2 Alpha, he would have treated plaintiff differently. Yet, the appellate court herein held (Appendix, pp. 16a-17a):

> "We disagree with the plaintiff's position that federal statutes and regulations establish Upjohn's duty in its violation of that duty. The federal statutes presented at trial and included in the jury instructions for consideration, were not a substitute for expert testimony. The statutes merely set forth, in general, a drug manufacturer's duty under the law. However to establish a violation of that duty expert testimony was required to define the terms and explain the manner in which they were to be applied."

Thus, the holding in this case returns the issues of adequacy and content of drug labeling to a debate ended by

Congress, and the Commissioner of Food and Drugs, who aggressively reinforced the meaning of that congressional mandate in 1974 and thereafter. In an era where potential financial profit motivates the biotechnical industry to market drugs rapidly, the federal statutory scheme and its enforcers stand as the only gatekeeper to protect the public by ensuring that information about all potential hazards associated with administration of a drug are adequately disseminated to physicians dispensing those drugs to the public. Where those laws are circumvented and the public is injured, private rights must be enforceable by reliance on the clear federal mandate to accurately label all ethical drugs. The appellate court holding will be utilized to frustrate the uniform application of that labeling law and will undermine the reliability of drug warnings and accountability for those violations of the law which produce catastrophic injury and death.

II.

PLAINTIFF HAS BEEN DENIED HER DUE PROCESS OF LAW WHERE HER RIGHT TO TRIAL BY JURY WAS TAKEN FROM HER.

Plaintiff's ward has complied with those procedural steps necessary to secure her a right to trial by jury throughout this litigation. The reversal of this judgment without remand for a new trial has eradicated that right at an advanced stage of the litigation, even though the Illinois Constitution reaffirms the Seventh Amendment right to trial by jury (Art. I §13); while there is no contention that state law could not be exercised to abridge that right, Illinois state law has not abridged that right, but instead confirmed the right to trial by jury.

Yet, the appellate court herein has denied plaintiff due process when the court departed from established law,

characterized issues as matters of first impression, created new evidentiary standards as to the competency of expert witnesses and concluded that plaintiff's expert was incompetent to testify. On the federal statutory issues, the court concluded that expert witnesses, and not the court, should interpret the meaning of law and duty. Finally, the appellate court fashioned these new evidentiary and factual precedents without providing a forum in which plaintiff could meet these issues which the court candidly acknowledges are matters of first impression. In denying plaintiff that forum, a new trial, the appellate court has denied plaintiff her due process right which protected her right to trial by jury. Plaintiff believes the issue raised here should apply the guarantee of due process afforded under the Constitution of the United States to the right to trial by jury, where the state constitution has secured that right to its citizens.

CONCLUSION

For the foregoing reasons, the *writ of certiorari* to the Appellate Court of the State of Illinois should be granted.

Respectfully submitted,

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APPENDIX

OPINION OF THE APPELLATE COURT

213 Ill.App.3d 390, 157 Ill.Dec. 566, 572 N.E.2d 1030 (1991)

The NORTHERN TRUST COMPANY, Successor Guardian of the Estate of Shelby Anderson Moran, a Disabled Person, Plaintiff-Appellee/Cross-Appellant,

v.

The UPJOHN COMPANY, Defendant-Appellant/Cross-Appellee (John J. Barton, M.D. and the Illinois Masonic Medical Center, Defendants-Appellants).

Nos. 1-89-2165, 1-89-2244 and 1-89-2357.

Appellate Court of Illinois, First District, Fifth Division.

April 26, 1991.

* * * * *

Justice MURRAY delivered the opinion of the court:

This opinion addresses the consolidated appeals brought by the Upjohn Company (Upjohn) (No. 89-2165), John J. Barton, M.D. (Dr. Barton) (No. 89-2357); and the Illinois Masonic Medical Center (IMMC or the hospital) (No. 89-2244), as well as the cross-appeal brought by the Northern Trust Company (Northern Trust), the successor guardian of the estate of Shelby Anderson Moran (Moran), a disabled person. The facts of the case are as follows:

At about 4 p.m. on January 24, 1978, Moran entered IMMC to have her pregnancy aborted. Although Moran had a history of high blood pressure (hypertension) and was taking medication to control this, her blood pressure upon entering the hospital that day was normal and she was observed, upon initial interview by Nurse Ping, to

be in generally good health, although she was somewhat overweight.

After Moran was prepared by Nurse Ping and an I.V. started, Dr. Barton came to the room to perform this procedure. The method chosen to accomplish the second-trimester pregnancy interruption was intrauterine administration of the drug Prostiglandin F2 Alpha (Prostin), which was manufactured and distributed by Upjohn.

Instillation of the Prostin began at about 4:20 p.m. and was completed at about 4:25 p.m. Dr. Barton then left the room to go to the nurses' station to write in Moran's chart. Initially, Moran suffered some of the side effects typically associated with the drug, including nausea, vomiting, cough, and irregular pulse rate. However, by 4:30 p.m. her blood pressure had elevated dramatically to 230 over 75. Dr. Barton was called back into Moran's room and notified of this change. At about 4:35 p.m., Dr. Barton returned to Moran's room to check on her. After making a physical assessment, he decided that Moran was having a mild reaction to the Prostin and instructed Nurse Ping to continue monitoring her closely. He then left the room.

At about 4:40 p.m. Moran's blood pressure seemed to have improved, but her pulse weakened, she became cyanotic, and she experienced shortness of breath. For this reason Nurse Ping started administering oxygen to Moran and attempted to notify Dr. Barton of this fact.

With the administration of oxygen, Moran's cyanosis did not improve, but she was sitting up and talking and appeared less anxious. Then, at about 4:55 p.m., Moran's blood pressure dropped very low and she "didn't look the same" to Nurse Ping. Dr. Barton was paged and, when he did not respond, Dr. Garbaciak, a resident obstetrician/gynecologist at the hospital, was called to check her. Dr.

Garbaciak responded immediately and as he entered the room Moran suffered a cardiac arrest.

Cardio-pulmonary resuscitation was begun and a "code blue" was called. The "code team" arrived immediately and Moran was ultimately resuscitated. However, because of the cardiac arrest, Moran sustained brain injury, which apparently involves permanent memory loss, disorientation, inability to understand abstract concepts, and difficulty in performing normal daily activities. There is some dispute over the exact nature of the brain injury. There is evidence that it may be organic in nature, *i.e.*, an irreversible physical condition resulting from oxygen deprivation to the brain. However, there was also some evidence that it is psychological in nature, *i.e.*, Moran may suffer from a psychiatric condition known as "conversion reaction", brought on by deep depression. It is also possible that Moran's non-communicative condition has components of both organic and psychiatric injury. In any event, Moran has required residential care in a nursing home environment since her release from IMMC.

In January 1980, Northern Trust filed a complaint in the circuit court of Cook County naming Upjohn, Dr. Barton and IMMC as defendants. Dr. Barton and IMMC were charged with medical malpractice, while Upjohn was charged with negligence and product liability. After years of discovery and pretrial activity, the cause proceeded to trial before a jury in 1989. The trial lasted eight weeks, after which the jury deliberated several days. They returned a general verdict in plaintiff's favor and against all defendants, jointly and severally, in the amount of $9,510,301. On April 14, 1989, the trial court entered judgment on the verdict. Post-trial motions were denied. All three defendants filed timely appeals and plaintiff cross-appealed.

This court consolidated the appeals in an order dated October 26, 1989, and oral argument was held March 12, 1991.

Initially, this court notes that on February 8, 1991, this court, on its own motion, entered an order that the parties show cause why the appeals should not be dismissed as nonfinal. This is because the trial court, in the order being appealed, retained jurisdiction to consider costs and fees and did not include the language that there was "no just reason for delaying enforcement or appeal," as set forth in Rule 304(a). (107 Ill.2d R. 304(a).) The order stated:

> "Further ordered that this court shall retain jurisdiction to approve Plaintiff's costs and fees pursuant to the local rules of the Circuit Court of Cook County, but that, in no way is such retention of jurisdiction intended to delay the force and effect of the judgment portion of this order."

It is a reviewing court's duty to determine whether it has jurisdiction to entertain an appeal, even if none of the parties raise the issue. (See *In re Custody of D.A.* (1990), 201 Ill.App.3d 810, 146 Ill.Dec. 1021, 558 N.E.2d 1355; *Illinois State Toll Highway Authority v. Gary-Wheaton Bank* (1990), 203 Ill.App.3d 672, 149 Ill.Dec. 99, 561 N.E.2d 377.) Consequently, before considering the merits of the appeals before us, we shall first address the question of whether this court has jurisdiction over them.

Recent case law has defined a request for attorney fees, whether pursuant to statute (see *Marsh v. Envangelical Covenant Church* (1990), 138 Ill.2d 458, 150 Ill.Dec. 572, 563 N.E.2d 459; attorney fees sought as a sanction under section 2-611 of the Civil Practice Law), or pursuant to a contract provision (see *Mars v. Priester* (1990), 205 Ill.

App.3d 1060, 150 Ill.Dec. 850, 563 N.E.2d 977; discretionary award of attorney fees requested under terms of contract), as a "claim" within the meaning of Supreme Court Rule 304(a). (107 Ill.2d R. 304(a).) Consequently, a trial court's retention of jurisdiction to hear such a claim makes any other judgment in the case nonfinal and nonappealable unless the language set forth in Rule 304(a), that no just reason to delay enforcement or appeal, has been inserted.

In the present case the trial court retained jurisdiction to consider the matter of attorney fees. However, it appears that the issue of attorney fees in this case was not a claim for fees made against the defendants. In this case the trial court retained jurisdiction to approve the proper distribution of the judgment award to cover plaintiff's cost of litigation, including attorney fees. Such court intervention in the distribution of the judgment award is necessitated by local Circuit Court Rule 6.4, concerning the disposition of pending cases involving minors or disabled persons.

For this reason we do not believe that the issue of attorney fees in this case is a "claim for relief" within the meaning of Rule 304(a). It is not a matter involved in the action nor does it represent a possible liability of the defendants. Consequently, we find that the judgment entered by the trial court was final despite the retention of jurisdiction to consider plaintiff's attorney fees and this court has jurisdiction to proceed with the merits of the appeals.

UPJOHN APPEAL

Upjohn raises six issues on appeal:

1. Whether the trial court erred by allowing plaintiff to place into evidence the 1981 package insert for Prostin.

2. Whether Upjohn was entitled to a directed verdict or judgment notwithstanding the verdict (JNOV) because plaintiff presented no expert testimony to establish the inadequacy of the warnings included in the package insert for Prostin in 1978.

3. Whether the verdict was against the manifest weight of the evidence because plaintiff failed to establish that the alleged failure to warn was the proximate cause of plaintiff's injury.

4. Whether the jury was improperly instructed on the matter of proximate cause.

5. Whether the trial court erroneously admitted certain testimony by Dr. Barton.

6. Whether remittitur or a new trial on damages should be granted because the amount of the verdict was unsupported by the evidence.

Initially we note that, prior to trial Upjohn filed a motion for summary judgment. At trial, at the close of plaintiff's case, Upjohn moved for a directed verdict and in a post-trial motion Upjohn moved for judgment notwithstanding the verdict. In each instance, it was Upjohn's contention that expert testimony was necessary to establish its liability and that because no expert had been presented by plaintiff to establish the inadequacy of the warning provided in the Prostin package insert, it was entitled to judgment in its favor. We agree.

There is no case law in Illinois which addresses the issue of whether expert testimony should be required in actions against drug manufacturers alleging a failure to adequately warn. There are, however, cases in other jurisdictions which establish the need for expert testimony in negligence and/or product liability actions involving prescription drugs, premised on the drug manufacturer's failure to warn. (See *Carlsen v. Javurek* (CA8 SD 1975), 526 F.2d 202; *Hill v. Squibb & Sons, E.R.* (1979), 181 Mont. 199, 592 P.2d 1383; *Dion v. Graduate Hospital of University of Pennsylvania* (1987), 360 Pa.Super. 416, 520 A.2d 876; *The Upjohn Company v. Macmurdo* (1990), 562 So.2d 680.) These courts have found that such a requirement is the logical extension of the fact that a prescription drug manufacturer's duty to warn is directed to the prescribing physician. For that reason, only a physician or someone with specialized knowledge would be qualified to determine whether the warning was inadequate. (See *Hill v. Squibb & Sons, E.R.*, 592 P.2d at 1388.) These courts have also held that requiring expert testimony in failure-to-warn cases involving prescription drugs is analogous to the expert testimony requirement in medical malpractice actions.

We observe that in Illinois it has already been determined that when dealing with prescription drugs, where the warning is being communicated to a physician who acts as a learned intermediary, the adequacy of the warning must be judged by whether it sufficiently appraises the prescribing physician of the risk associated with the use of the drug. (*Kirk v. Michael Reese Hospital and Medical Center* (1987), 117 Ill.2d 507, 111 Ill.Dec. 944, 513 N.E.2d 387; *Mahr v. G.D. Searle & Co.* (1979), 72 Ill.App. 3d 540, 28 Ill.Dec. 624, 390 N.E.2d 1214.) It is also necessary in Illinois to present expert testimony in medical mal-

practice actions. (*Purtill v. Hess* (1986), 111 Ill.2d 229, 95 Ill.Dec. 305, 489 N.E.2d 867; *Walski v. Tiesenga* (1978), 72 Ill.2d 249, 256, 21 Ill.Dec. 201, 381 N.E.2d 279.) Based upon this established Illinois law, we now adopt the rationale of the courts in the other jurisdictions cited above and hereby hold that, by logical extension, expert testimony shall be necessary and proper in a case, such as the one at bar, where a drug manufacturer's liability for a prescription drug is based upon its failure to provide adequate warnings. We note, however, that our decision, as in the cases cited above, is limited to those instances where the inadequacy of the warning is not so obvious that a lay person could not readily understand the insufficiency of the warning. (See *Dion v. Graduate Hospital of University of Pennsylvania*, 520 A.2d at 881, expert testimony requirement limited to those cases in which the meaning of the warning eludes the comprehension of the ordinary lay person.) Consequently, we must now consider whether expert testimony was required in the present case or whether the alleged failure to warn was of a type that would allow a jury to reach an intelligent conclusion about the adequacy of the warning without the aid of an expert's specialized knowledge.

In the present case, plaintiff amended its complaint a number of times. However, with respect to the action against Upjohn, the theories of recovery that were ultimately submitted to the jury were, (1) that Upjohn was negligent in the marketing and selling of Prostin because (a) Upjohn failed to inform physicians that cardiac arrest was associated with the use of Prostin, and (b) Upjohn failed to inform physicians that possible adverse reactions were not transient; (2) that Prostin, at the time it left Upjohn's control, was in an unreasonably dangerous condition in that (ε) its product labeling insert did not warn

physicians that cardiac arrest was associated with the use of Prostin, (b) the product insert informed physicians that adverse reactions were transient, (c) the therapeutic profile did not warn physicians that cardiac arrest was associated with the use of Prostin, and (d) the therapeutic profile informed physicians that adverse reactions were transient.

The jury was also instructed that it could consider whether Upjohn violated any statute, regulation or ordinance when deciding whether it was negligent and/or manufactured an unreasonably dangerous product. The statute being referred to, and which was quoted in pertinent part in the instructions to the jury, was entitled "Misbranded drugs and devices". (Title 21, U.S.C. Sec. 352(a), (f), (j), and (n).) The statute provides that a drug would be considered misbranded if its labeling was found to be false or misleading or if it failed to contain "adequate directions for use". The regulation referred to and quoted in the jury instructions, indicates that the labeling of a drug or device would be deemed misleading if it failed to reveal facts that were "material in light of other representations made . . . or with respect to consequences which may result from use . . ." The regulation also indicates that changes in labeling, advertising or warnings concerning a drug's contraindication or side-effects should be "placed into effect at the earliest possible time." 21 C.F.R. secs. 1.3(a)(1), (2); 314.8(a), (b), (d), (e) and (*l*).

At trial plaintiff attempted to show that cardiac arrest and/or death were possible side effects associated with the drug Prostin, that Upjohn was aware or should have been aware of the association between cardiac arrest and the use of its drug Prostin, but that Upjohn failed to include this possible side effect in its package insert, making the drug unreasonably unsafe or "defective". To this end,

plaintiff presented testimony and other evidence that prior to 1978 there were a number of cases[1] known to Upjohn where cardiac arrest and/or death had occurred during second trimester abortions in which the drug Prostin had been utilized.

Upjohn, however, disputed the contention that its knowledge that instances of cardiac arrest had occurred in correlation with the use of Prostin, was equivalent to knowledge that cardiac arrest was a "side effect" of Prostin so that it was obligated to list it as an adverse reaction in its package insert. Upjohn also argued that the omission of the term "cardiac arrest" from the list of adverse reactions in the package insert did not make the warning ineffective or inadequate.

When a plaintiff attempts to prove that a drug manufacturer failed to adequately warn, he must first demonstrate that there was a duty to warn. (*Mahr v. G.D. Searle &*

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[1] Prostin was approved by the FDA and placed on the market in 1973. After obtaining FDA approval Prostin was tested in clinical trials with over 7300 patients, none of whom experienced a cardiac arrest.

At trial plaintiff presented evidence that in May 1976 a paper was presented at the 24th Annual Meeting of the College of Obstetricians and Gynecologists wherein four (4) incidents of cardiac arrest and death were indicated to be "associated" with Prostin. However, the paper also indicated that Prostin "may have had only tangential association with the chain of events leading to any of the deaths." The total number of instances of cardiac arrest which may have occurred in conjunction with the use of Prostin between 1973 and 1978 is unclear. It is also unclear whether Upjohn was made aware, either through doctor experience reports or other communications, of every instance of cardiac arrest which occurred. However, from the evidence at trial it appears that Upjohn was aware of as many as nine instances where cardiac arrest and/or death occurred during second trimester abortions in which Prostin was used.

Co. (1979), 72 Ill.App.3d 540, 28 Ill.Dec. 624, 390 N.E.2d 1214.) Thus, in this case it was plaintiff's initial burden to show that cardiac arrest was, in fact, a reaction caused by the use of the drug Prostin. (See *Mahr*, 72 Ill.App.3d at 561, 28 Ill.Dec. 624, 390 N.E.2d 1214.) Additionally, following such a showing, plaintiff was required to plead and prove that Upjohn knew or should have known that cardiac arrest was a possible reaction caused by Prostin, but failed to warn of that fact. (*Woodill v. Parke Davis & Co.* (1980), 79 Ill.2d 26, 37 Ill.Dec. 304, 402 N.E.2d 194.) Finally, plaintiff was required to show that the omission of such information made the warning inadequate and the drug "defective" and that this defect was the proximate cause of plaintiff's injuries. Of course, it should be recalled that because the case involves prescription drugs where the warning is being communicated to a physician who acts as a learned intermediary, the duty to warn is directed to physicians and the adequacy of the warning must be judged by whether it sufficiently appraises physicians of the risks associated with the use of the drug. *Kirk v. Michael Reese Hospital and Medical Center* (1987), 117 Ill.2d 507, 111 Ill.Dec. 944, 513 N.E.2d 387; *Mahr v. G.D. Searle & Co.* (1979), 72 Ill.App.3d 540, 28 Ill.Dec. 624, 390 N.E.2d 1214.

This court finds that the question of whether Upjohn's knowledge of reported cases of cardiac arrest was tantamount to knowledge of an "association" between the drug and cardiac arrest which obligated it to include cardiac arrest as a possible side effect, was a complex question which required expert testimony. To the extent that Dr. Ischler, an employee of Upjohn, was an expert on this subject, his testimony failed to establish Upjohn's breach of duty. Dr. Ischler's testimony indicated that there was no magic formula used for deciding when an adverse re-

action must be included in a warning. Dr. Ischler also testified that deciding what information concerning reactions to a drug should be reported, depends on a "medical interpretation of the events." Even though Upjohn "could have" included cardiac arrest in its warning, this is not the same as saying that Upjohn breached its duty because it omitted cardiac arrest from the list of reactions.

Both Dr. Lesch, a cardiologist presented by Upjohn and Dr. King, an obstetrician/gynecologist who testified on behalf of Dr. Barton, seemed to indicate that the evidence regarding Moran, as well as the drug experience reports and other evidence admitted at trial with regard to Prostin, might indicate that cardiac arrest was not, itself, the adverse reaction as much as the result of other adverse reactions such as vomiting, bronchospasm, convulsion or heart block, which were listed by Upjohn as adverse reactions associated with the drug. Also, there was evidence that, despite the fact that cardiac arrest occurred after the administration of Prostin, the presence of pre-existing conditions in some of the patients who experienced cardiac arrest had to be taken into consideration since they could have been implicated as the causal factor in bringing about the cardiac arrest. In any event, it seems clear that the link between Prostin and cardiac arrest was not so apparent that expert testimony was not necessary to establish that a duty was imposed upon Upjohn to include cardiac arrest in the warnings based upon its knowledge that a small number of cardiac arrests had occurred in conjunction with the use of Prostin.

We realize that plaintiff introduced the 1981 insert, which had been amended to include information concerning the incidence of cardiac arrest, to establish the link between Prostin and cardiac arrest. However, we find this, too, was error. Although the question of whether

post-occurrence warnings are admissible in failure to warn product liability cases involving prescription drugs is one of first impression in this State, we find persuasive other authorities which have contemplated the matter. (*Werner v. Upjohn Co.* (CA4 1980), 628 F.2d 848; *De Luryea v. Winthrop Laboratories* (CA8 1983), 697 F.2d 222; *Smith v. E.R. Squibb & Son* (1976), 69 Mich.App. 375, 245 N.W. 2d 52, *aff'd* 405 Mich. 79, 273 N.W.2d 476.) These courts rejected the notion that post-occurrence warnings were admissible, finding them to be inappropriate. We agree.

In this case the salient question was whether Upjohn knew, prior to 1978, that cardiac arrest was associated with the use of the drug Prostin. Consequently, what Upjohn knew or included in its warnings after 1978 was irrelevant and only served to confuse and prejudice the jury against Upjohn. See *e.g. Gaenzele v. B.E. Wallace Products Corp.* (1976), 39 Ill.App.3d 93, 250 N.E.2d 571.

Finally, even if we were to assume that the evidence that was presented at trial was sufficient to advise the typical lay person that there existed a correlation between the drug Prostin and cardiac arrest sufficient to impose upon Upjohn a duty to warn, there is still the question of whether Upjohn abrogated its duty, *i.e.*, whether it was enough for plaintiff to present evidence that Upjohn did not inform physicians via product insert or other means, that cardiac arrest was a possible side effect of the use of the drug Prostin. This question, too, required expert testimony since we believe that the real issue was not whether the term "cardiac arrest" was listed among the side effects, but rather, whether the package insert and other materials designed to warn physicians of the possible risks associated with the drug, were adequate to advise *a physician* of the potential dangers that were inherent in the use of the product, despite the fact that

cardiac arrest was not listed *specifically* as a possible side effect of the drug.

In the 1976 package insert included with the drug Prostin, the following information was provided:

INDICATIONS

Prostin F2 Alpha (dinoprost tromethamine) is indicated for terminating second trimester pregnancy by the intra-amniotic administration of the drug. In a group of 229 patients, using the recommended dosage, 86.0% aborted completed, 12.2% incompletely and 1.8% failed to abort.

CONTRAINDICATIONS

1. Hypersentivity to Prostin F2 alpha (dinoprost tromethamine).

2. Acute pelvic inflammatory disease.

WARNINGS

Prostin F2 alpha as with other potent oxytocic agents, should be used ONLY with strict adherence to recommended dosages, by medically trained personnel in hospital surroundings which provide immediately-available intensive care and acute surgical facilities. Evidence from some animal studies has suggested that certain prostiglandins may have some teratogenic potential. Therefore, any failed pregnancy termination with Prostin F2 alpha should be completed by some other means.

ADVERSE REACTIONS

The most frequent adverse reaction observed with the use of Prostin F2 alpha (dinoprost tromethamine) for abortion are related to its contractile effect to smooth muscle.

In the entire group of patients studied, approximately one-half experienced vomiting, one-quarter some nausea, and about one-fifth diarrhea. Other

adverse effects, occurring from 2.7% to 0.1%, in decreasing order of frequency include:

Pain (other than uterine)
- Unspecified
- Epigastric
- Substernal, chest
- Leg
- Shoulder

Brachycardia
Headache
Flushing
Backache
Dizziness
Dyspnea
Posterior cervical perforations
Chills
Endometritis
Diaphoresis
Coughing
Hot flash
Wheezing
Convulsions
- Grand mal
- Possible epilitiform

Parathesia
- Unspecified
- of leg

Hypertension
Hyperventilation
Breast tenderness
Burning sensation
- In breast
- In eye

Chest constriction
Urine retention
Uterine rupture
Anxiety
Bronchospasm
Rales in chest

Diplopia
Drowsiness
Dysuria
Hematuria
Hiccough
Malaise
Polydipsia
Vasomotor symptoms
Vasovaginal symptoms
2nd degree heart block

Under the Precautions section it also stated that "in patients with a history of asthma, glaucoma, hypertension, cardiovascular disease or past history of epilepsy, Prostin F2 alpha should be given with caution.

As noted earlier, evidence at trial indicated that cardiac arrest could have resulted from several of the side effects already listed in the package insert. Furthermore, it seems clear that the meaning and medical implications of several of the listed adverse reactions is outside the knowledge of the ordinary lay person. For this reason it was necessary to submit expert medical testimony to establish the inadequacy of the warning.

In light of the fact that plaintiff in this case failed to present expert testimony to establish the inadequacy of these warnings and, moreover, that experts provided by Upjohn and others, *i.e.* Dr. Gianopoulos and Dr. King, testified that the warnings provided in the 1978 package insert for Prostin adequately warned physicians of the known risks associated with the drug Prostin, we find that plaintiff failed to prove its case against Upjohn and that a directed verdict or judgment notwithstanding the verdict should have been granted to Upjohn.

We disagree with plaintiff's position that the Federal statutes and regulations established Upjohn's duty and

its violation of that duty. The Federal statutes presented at trial and included in the jury instructions for consideration, were not a substitute for expert testimony. The statutes merely set forth, in general, a drug manufacturer's duty under the law. However, to establish a violation of that duty, expert testimony was required to define the terms and explain the manner in which they were to be applied. A lay person would be unable to determine, for example, whether a drug was "misbranded" unless expert testimony was provided. Without expert testimony a decision would be conjecture. Furthermore, the typical juror would be unqualified to determine, without the aid of expert testimony, whether the failure to include "cardiac arrest" was a "material misrepresentation," as defined by the statute, which made the warnings false, misleading or inadequate to direct the drug's usage.

Based upon our decision to reverse the judgment against Upjohn, we find it unnecessary to address the other issues raised in Upjohn's appeal or plaintiff's cross-appeal, in which plaintiff argued that it was error for the trial court to have directed a verdict in Upjohn's favor on the issue of punitive damages. This court's finding that there was insufficient evidence to prove that Upjohn's failure to include cardiac arrest in the drug warning constituted a failure to warn, would also preclude a finding that its failure to include cardiac arrest in the warning constituted wanton and willful misconduct. Therefore, we affirm the trial court's ruling on the punitive damages issue and now turn our attention to the appeals brought by Dr. Barton and IMMC.

DR. BARTON'S APPEAL

Although Dr. Barton raises a number of issues in his appeal, essentially, he questions the qualifications of the

expert used by plaintiff to establish the applicable standard of care, the sufficiency of the evidence indicating that plaintiff's injury was proximately caused by his conduct, and a number of evidentiary rulings of the trial court which could have affected the damage award. We shall first address the issue concerning the expert testimony presented by plaintiff.

It is undisputed by the parties that, in a medical malpractice action, it is the plaintiff's duty to establish the proper standard of care to be applied to a defendant-doctor's conduct, a breach of that standard, and a resulting injury proximately caused by the breach of care. (*Purtill v. Hess* (1986), 111 Ill.2d 229, 95 Ill.Dec. 305, 489 N.E. 2d 867.) Additionally, unless the alleged negligence is so grossly apparent or within the common knowledge of a lay person, expert testimony is required to establish the standard of care and its breach. (*Novey v. Kishawaukee Community Health Service Center* (1988), 176 Ill.App.3d 674, 126 Ill.Dec. 132, 531 N.E.2d 427.) When an expert is offered to establish the applicable standard of care and breach, a two-part test is used to determine the admissibility of the expert testimony. (*Bartimus v. Paxton Community Hospital* (1983), 120 Ill.App.3d 1060, 76 Ill.Dec. 418, 458 N.E.2d 1072.) First, it must be shown that the expert is licensed in the same "school of medicine" to which the defendant-doctor belongs. (*Dolan v. Galluzzo* (1979), 77 Ill.2d 279, 32 Ill.Dec. 900, 396 N.E.2d 13; *Witherell v. Weimer* (1986), 148 Ill.App.3d 32, 101 Ill.Dec. 679, 499 N.E.2d 46.) Secondly, the expert must demonstrate that he is otherwise qualified to give expert testimony on the case.

As stated in *Novey*, the "school of medicine" doctrine dictates that "the expert who establishes the practitioner's deviation from the pertinent standard of care must be

both a licensed member of the school of medicine about which he opines and familiar with the ordinary methods, procedures, and treatments of the practitioners in the actual or similar community unless certain uniform standards apply regardless of either locality or available conditions or facilities." (176 Ill.App.3d at 678.) In this case, plaintiff's expert, Dr. Mathews, was licensed to practice medicine in the State of Illinois and employed as the director of emergency services at Northwestern Memorial Hospital. He testified that he was board certified in internal medicine and emergency medicine. It seems clear, therefore, that Dr. Mathews is licensed in the same "school of medicine" as Dr. Barton and that the first prong of the test for admission of expert testimony was satisfied.

However, it is the second prong of the test that presents problems for this court. Dr. Mathews testified that he was not an obstetrician or gynecologist and that his specialty was emergency medicine. Although he had testified as an expert in several cases, he stated that those cases involved the assessment and response to acute problems, such as would be seen in the emergency room. He had never worked in an obstetrical or gynecological ward, had attended patients delivering babies "on occasion", but apparently had never been involved in pregnancy interruption procedures. He had never used the drug Prostin, never seen it used and never observed the reactions of a patient receiving the drug. In fact, he had never had any experience with the drug in any manner and had not even read the insert and profile for the drug until he was asked to testify in the case. For these reasons this court finds that Dr. Mathews was not competent to testify on the standard of care to be applied to Dr. Barton.

We realize, as plaintiff argues, that Dr. Mathews' criticism of Dr. Barton centered around his assessment of his

patient and not his administration of any gynecological procedure. However, Dr. Barton's assessment of his patient should not be taken out of context of the setting in which it was made since the issue is whether he deviated from the accepted or customary medical standards at the time and place that the event occurred. Dr. Mathews was not qualified to give an opinion on this since he could not know what was customary practice for someone in Dr. Barton's position.

As stated in *Stevenson v. Nauton* (1979), 71 Ill.App.3d 831, 28 Ill.Dec. 71, 390 N.E.2d 53, to establish a *prima facie* case requires more than the mere presentation of testimony from another physician who would have acted differently. It requires testimony that the doctor deviated from established procedures. Dr. Mathews, whose experience was in the delivery of emergency care to acutely ill patients may have reacted to the vital signs and symptoms of the plaintiff here in a distinctively different manner than the manner in which an obstetrician/gynecologist performing second trimester pregnancy interruptions would have reacted.

Consequently, we find that the plaintiff failed to present sufficient expert testimony to establish the standard of care and the breach of that standard, and so we reverse the judgment entered against Dr. Barton.

ILLINOIS MASONIC MEDICAL CENTER

Initially, it should be noted that plaintiff's negligence action against IMMC was based on (1) the negligent conduct of Nurse Ping and (2) the medical malpractice of Dr. Barton, who was alleged to be an employee of the hospital. A general verdict was entered against all defendants and so it is impossible to distinguish on what basis the

jury held IMMC responsible for plaintiff's injuries. Because of this and the fact that this court has already reversed the judgment against Dr. Barton, IMMC is entitled, at the very least, to a new trial. However, we must determine whether IMMC has presented any issues to this court which would warrant reversal of the judgment entered against it.

The determinative issue here is whether there was sufficient evidence presented at trial of the negligence of IMMC through its agent, Nurse Ping. IMMC claims that there was not. We agree.

In negligence actions of this type it is the plaintiff's duty to establish the standard of care that the hospital is required to meet, the deviation from that standard of care, and the manner in which the deviation resulted in harm to the plaintiff. (*Mielke v. Condell Memorial Hospital* (1984), 124 Ill.App.3d 42, 79 Ill.Dec. 78, 463 N.E.2d 216.) The standard of care applicable to a hospital may be proven "via a number of evidentiary sources" (*Mielke*, quoting *Greenberg v. Michael Reese Hospital* (1980), 83 Ill.2d 282, 294, 47 Ill.Dec. 385, 415 N.E.2d 390), including expert testimony.

In this case plaintiff attempted to show and the jury was instructed, that IMMC was negligent because: (1) its nursing personnel failed to obtain the presence of a physician from 4:40 to 4:55 p.m., and (2) its nursing personnel failed to "appreciate the existence of an emergency represented by the events described up to and including [Moran's] failure to improve with oxygen."

Plaintiff presented its expert, Dr. Mathews, to establish the standard of care and the deviation from that standard. However, a review of his testimony reveals that Dr. Mathews did not conclusively establish the applicable

standard of care, nor did he establish Nurse Ping's deviation from that standard.

At trial plaintiff's attorney asked Dr. Mathews:

> "Q. Doctor, based upon this record and the condition of the patient, do you—of what significance is it to you, if any, in formulating your opinions regarding Nurse Ping that a physician was not present until 4:55?"

Doctor Barton responded:

> "A. You know, if it was—let's—if it was 4:45, I wouldn't be concerned because I think that's a reasonable response for the nurse to what was done at 4:40.
>
> It seemed to me, however, that that was—and it is my opinion, that that was one of the major parts of what her responsibility here.
>
> I believe we discussed the two things I thought were critical actions here. One was to take some emergency steps to relieve this woman's problem, which was done in the form of, at least, some oxygen was started. And secondly, to contact a physician for help."

However, upon cross-examination, it was learned that Dr. Mathews had not read Nurse Ping's trial testimony and he was not able to determine from the record what Moran's condition was between 4:45 and 4:55 p.m. In fact, he admitted that it was impossible to tell from the record when things actually happened because the record was not written simultaneously with the events, but rather was a retrospective account. For this reason it was difficult to determine at what point Moran's condition worsened to the point that intervention by a doctor should have been sought by Nurse Ping.

Dr. Mathews also testified that he would expect a nurse to use her past experience when exercising her judgment in deciding when an emergency existed and when it was necessary to call for a doctor or emergency assistance. Furthermore, he admitted that he was unfamiliar with the drug, Prostin, and the normal reactions to the drug which were typically observed by nurses and doctors working with the drug on a regular basis. For this reason, this court believes that Dr. Mathews was not qualified to establish and did not establish the standard of care that was applicable to Nurse Ping or her deviation from that standard.

By the same token, Dr. Gianopoulos, a practicing obstetrician and gynecologist, as well as a professor in obstetrics at Loyola University Medical Center, testified that when looking at the entire picture rather than isolated incidents, Nurse Ping acted appropriately and within the standard of care. The same opinion was expressed by Dr. King, an obstetrician and gynecologist who taught at Johns Hopkins School Of Medicine and had extensive experience with Prostin. He stated that, based upon his clinical experience with the drug Prostin, the signs and symptoms observed by Nurse Ping between the time of the instillation and the cardiac arrest, were "characteristically thought of in that era of being transitory in nature." In fact all of the experts, even Dr. Mathews, admitted that cardiac arrest can occur without warning and without negligence on the part of the persons attending the patient.

Viewing all of the evidence, we conclude that the manifest weight of the evidence did not support the finding that Nurse Ping was negligent and so we reverse the judgment entered against IMMC.

For all the reasons stated above the judgment entered in favor of the plaintiff and against the defendants is reversed.

REVERSED.

GORDON and McNULTY, JJ., concur.

LETTERS FROM THE SUPREME COURT OF ILLINOIS

October 2, 1991

Mr. James H. Canel
Attorney at Law
30 N. LaSalle St., S#1740
Chicago, IL 60602

No. 71892—The Northern Trust Company, etc., petitioner, v. The Upjohn Company et al., respondents. Leave to appeal, Appellate Court, First District.

The Supreme Court today DENIED the petition for leave to appeal in the above entitled cause.

The mandate of this Court will issue to the Appellate Court on October 24, 1991.

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November 4, 1991

Ms. Patricia N. Hale
Attorney at Law
30 N. LaSalle, Suite 1740
Chicago, IL 60602

THE COURT HAS TODAY ENTERED THE FOLLOWING ORDER IN THE CASE OF:

No. 71892—The Northern Trust Company, etc., petitioner, v. The Upjohn Company et al., respondents.

The motion by petitioner for leave to file a motion for reconsideration of the order denying the petition for leave to appeal is *denied.*

JH:bko

cc: Hinshaw & Culbertson
Pretzel & Stouffer (Neil K. Quinn)
Johnson & Bell (William V. Johnson)

PORTIONS OF THE RECORD RELIED UPON IN WHICH THE FEDERAL QUESTIONS SOUGHT TO BE REVIEWED WERE RAISED

Excerpted Portions Of The Petition For Leave To Appeal Relied Upon

Parts 1(a)(b), page 3:

I. The Plaintiff is entitled to appeal as a matter of right under Rule 317, as a result of the appellate court's opinion in this case.

a. The appellate court reversed the jury's verdict but did not remand for a new trial. That action violated plaintiff's fundamental right to trial by jury, Ill.Const., 1970, Art. I §13.

b. The appellate court, in weighing the evidence, applied a new but unarticulated standard different than the *Pedrick* standard. This new standard focused on testimony quoted in the court's opinion (Sl. Op. 24), but that testimony was never considered by the jury when it decided this case. It had been stricken from the record, unlike the other 233 pages of the expert's testimony not stricken, which the jury did consider together with all the other evidence. The appellate court denied plaintiff equal protection of the law guaranteed by Ill.Const. 1970, Art. I §2 and U.S.C.A. Const. Amends. XIV when it failed to weigh the evidence considered by the jury, but instead went outside the evidence and seized upon stricken testimony to decide the case.

Part 2(b) and (b)(i), pp. 3-4:

II. The Supreme Court should exercise its discretion to grant leave to appeal under Rule 315 for the reasons set forth in I above, and:

b. The appellate court, in claiming matters of first impression, disregarded a substantial body of decisional law when it held:

(i) That a violation of a statute intended to protect the public health, the violation of which is a proximate cause of an injury to the plaintiff, is **not** *prima facie* evidence of negligence;

Pages 26-29:

5. Argument

Prefatory Statement

The appellate court reversed, *without remand*, this $9,510,301 verdict in favor of Shelby Anderson Moran, a disabled person, against all of the defendants for reasons which are unsupported by any Illinois precedent, by the appellate court's own admission, unsupported by this 5,500 page report of proceedings and 4,600 page common law record, and unsupported by established Illinois precedent. Among other things, the court held that a violation of a specific federal statutory scheme intended to protect the public safety is not *prima facie* evidence of negligence unless an "expert" says so; that an "expert witness" must interpret the law in a product liability case against a drug company; that a licensed and double board certified physician is incompetent to testify as an expert when his testimony addresses basic principles of medicine universal to the delivery of health care by either a physician, or a hospital, through its nursing personnel; and that if that expert finds a deviation from the standard of care, and resultant injuries, the plaintiff has still somehow failed to bear her burden to make a *prima facie* case. Plaintiff respectfully submits that the appellate court's opinion constitutes such a radical departure from the law of the State

of Illinois that it is virtually a trip to the legal land of Oz. False analogies, misstated facts, incomplete, garbled or stricken testimony and oversimplification of the issues presented form the "bases", as it were, for the appellate court's opinion. Further, this opinion, which essentially grants all the defendants a judgment notwithstanding the verdict, without remand for application of the "issues of first impression" created by the appellate court, is all the more remarkable for its absence of any discussion of *Pedrick v. Peoria Railway Company* (1967) 37 Ill.2d 494, 229 N.E.2d 504, although that case has been cited 426 times in Illinois and creates the standard by which verdicts ought to be directed and judgments *n. o. v.* entered, only when all of the evidence, viewed in its aspect most favorable to the opponent, so overwhelmingly favors movant that no contrary verdict based on that evidence could ever stand. As to the ultimate result in the appellate court, Plaintiff respectfully submits that it is unsupported by the facts of the case, by the law of the State of Illinois, and is a departure from both the facts of the case presented to the jury and the applicable case law of Illinois.

The appellate court treated some issues as matters of first impression by ignoring the existing and established precedent on controlling issues already articulated by this court, and failed to follow the holdings of other divisions of the appellate court in the same district. Where this court has decided a point, the appellate court must follow this court's authority. Where the same appellate court district has decided a matter, the appellate court should follow that precedent. When it fails to do so, that undermines the ability of lawyers and judges to rely on established precedent, creating confusion as to how the trial court should proceed in deciding similar cases when different divisions of the appellate court decide the same issue

differently. *Agricultural Transp. Assn. v. Carpenter* (1953) 2 Ill.2d 19, 116 N.E.2d 863, 867; *People v. Palmer* (1st Dist. 1986) 141 Ill.App.3d 234, 490 N.E.2d 154, 158; *Sidwell v. Griggsville Com. School D. No. 4* (4th Dist. 1991) 208 Ill.App.3d 296, 566 N.E.2d 838, 840; *Walton v. Norphlett* (1st Dist. 1977) 56 Ill.App.3d 4, 371 N.E.2d 978, 979. That departure is most apparent in the appellate court's holding regarding the competence of an expert witness, the standard to be applied in its manifest weight of the evidence analysis, and its holding with respect to Upjohn's statutory violations.

Further, when this court has found it necessary to decide matters of first impression on evidentiary issues, this court has observed that it would be "unfair to hold them applicable to the plaintiff in the instant case."[1] This court has remanded so that the matter of first impression, now decided, would be applied to the case on remand. *Wilson v. Clark* (1981) 84 Ill.2d 186, 417 N.E.2d 1322, 1327, citing and relying upon *Stevens v. Silver Manufacturing Co.* (1977), 70 Ill.2d 41, 46, 15 Ill.Dec. 847, 374 N.E.2d 455; *Renslow v. Mennonite Hospital* (1977), 67 Ill.2d 348, 359, 10 Ill.Dec. 484, 367 N.E.2d 1250; *Molitor v. Kaneland Community Unit District No. 302* (1959), 18 Ill.2d 11, 26-27, 163 N.E.2d 89. What follows is a detailed analysis of the reasons why leave to appeal is appropriate in this

[1] This case is a perfect example of why it would be unfair. Plaintiff's reliance on the case law at trial (as well as the trial court, when it denied Dr. Barton's motion to bar Dr. Mathews because he was not an obstetrician/gynecologist) prompted the plaintiff not to call Dr. Phelan who was an obstetrician/gynecologist with abortion experience using Prostin (C2924-C2925, C2927, C2929) because of scheduling (C2282-C2285); he was not critical of the abortion procedure done by Dr. Barton (C2936), but testified both Dr. Barton and the hospital deviated from the standard of care immediately following the procedure. (C2996)

case under Rule 315, and is required as a matter of right under Rule 317.

* * *

Pages 58-67:

The Statutory Duty The Upjohn Company Violated Was Very Specific and Intended to *Prevent* the Very Problem Which was Central to its Misdeed Here.

The statutory and regulatory scheme imposed on Upjohn (and other drug manufacturers) a duty to warn doctors about potential adverse reactions whether or not a cause and effect relationship was established. Contrary to the appellate court's characterization of that law as general, it is explicit. The failure to comply was a violation of law; that law established the legal standard by which the jury decided Upjohn's obligation to Shelby Moran. Title 21, U.S.C. Section 352 (a)(f)(j)(n) "Misbranded Drugs and Devices"; 21 C.F.R. Section 1.3 (a)(1)(2), Section 314.8 (a)(b)(d)(1)(e), and the Commissioner of the Food and Drug Administration's interpretation of the regulation as reported in the Federal Register, Vol. 39, No. 80, Monday, September 16, 1974 at 39 FR 33230-33233; 40 FR No. 130, Monday, July 7, 1975, 40 FR 28582-28586 and Vol. 44, No. 124, Tuesday, June 26, 1979, 44 FR, 37447-37448 firmly imposed upon Upjohn the precise duty to disclose in its labeling warnings that a drug "may be dangerous to health." The Commissioner repeatedly and explicitly rejected the argument that the statute and regulation could be interpreted to impose a duty to warn only after a causal connection was first established. The Commissioner stated, 40 FR 28583:

> "The statute requires that a warning be placed on the label when there is a *potential* hazard, as well as when there is proof of a causal relationship between the hazard and the drug. The Congressional

> requirement of a clear drug warning of these circumstances assures that a *potential* hazard will be brought to the attention of the physicians . . ." (Emphasis added)

In June of 1979 the Commissioner restated what he said in 1975, 44 FR 37448:

> "The statutory scheme for drug labeling requires that **potential** hazards, as well as a **known** hazard, be included in labeling." (Emphasis added)

Upjohn's violation of federal law regulating its labeling of Prostaglandin F_2 Alpha constituted *prima facie* evidence of negligence. See: *Ney v. Yellow Cab* (1954) 2 Ill.2d 74, 117 N.E.2d 74, 78; *Davis v. Marathon Oil* (1976) 64 Ill.2d 380, 356 N.E.2d 93, 97-98; *French v. City of Springfield* (1976) 65 Ill.2d 74, 357 N.E.2d 438, 440-441. Those same violations provide a standard by which the issue of whether the product is defective was decided by the jury. *Rucker v. Norfolk & W. Ry. Co.* (1979) 77 Ill.2d 434, 396 N.E.2d 534, 536-537; *Byrne v. SCM Corp.* (4th Dist. 1989) 182 Ill.App.3rd 523, 538 N.E.2d 796, 810-813. Where there is a violation of statutes and regulations, proof of that violation establishes the breach of duty, not expert testimony. *Northern Trust Co. v. Louis A. Weiss Memorial* (1st Dist. 1986) 143 Ill.App.3d 479, 493 N.E.2d 6, 13.

Upjohn's Breach of a Statutory Duty Created a Question of Fact for the Jury.

The appellate court is apparently convinced that juries can only reach "intelligent conclusions" about the adequacy of a warning if an expert decides the issues for them, although this is *not* the law of medical malpractice cases in Illinois, as the appellate court so casually states. In reaching its "expert witness" requirement in drug

litigation, which the court admits is a case of first impression in Illinois, the appellate court relies upon four cases from other jurisdictions. They are: *Carlsen v. Javurek* (CA8 SD 1975), 526 F.2d 202; *Hill v. Squibb & Son, E.R.* (1979), 181 Mont. 199, 592 P.2d 1383; *Dion v. Graduate Hospital of University of Pennsylvania* (1987), 360 Pa. Super. 416, 520 A.2d 876;[2] *The Upjohn Company v. Macmurdo* (1990), 562 So.2d 680. These cases do not support any change in the law, and in any event they are all distinguishable from the instant case. There is a *fatal flaw* in the reasoning of the appellate court, especially in its reliance upon the cases cited for the proposition that plaintiff must produce expert testimony to prove a strict liability case against the manufacturer of an ethical drug (while ignoring the evidentiary import of a mandatory federal statute). Strikingly, a close examination of all those foreign cases cited by the appellate court reveals that *not one* evolved out of either alleged statutory violations, or the evidentiary role of alleged statutory violations, in establishing the duty of a drug manufacturer to warn, and the adequacy of any warnings given, in the manufacture and marketing of an ethical drug. Unlike those cases relied on by the appellate court, the statutory violations were central to the plaintiff's theory of liability against Upjohn which was developed in reliance of the established body of law.

The Upjohn Company's violation of the statutory and regulatory duty imposed upon it to warn of the potential of cardiac arrest and death associated with the use of Pro-

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[2] Where a statutory violation is at issue, Pennsylvania law is completely harmonious with the law of Illinois; see *Stanton v. Astropharmaceutical Products, Inc.* (CA 3rd Cir. 1983) 718 F.2d 553, 565, cited at page 66 *infra*, applying Pennsylvania law.

staglandin F_2 Alpha is *prima facie* evidence of their liability, and supports the jury's verdict. Upjohn does not challenge the applicability of that law to its conduct here, because it does not claim the court erred in giving plaintiff's instruction 37 which set forth in detail those provisions of Title 21, USC §352 and 21 CFR 1.3(a)(1)(2); 314.8(a)(b)(d)(1)(e) (A39-41 plaintiff's instruction 37).

In light of the statutory and regulatory obligations imposed upon The Upjohn Company, its position that it had no duty to warn about the possible association between Prostaglandin F_2 Alpha and cardiac arrest and death is untenable. The identical contention was advanced by the drug industry in general for a number of years; it was unequivocally rejected by the Commissioner of the Food and Drug Administration. In 1974, the Commissioner reviewed the legislative history of those statutory requirements of the Code of Federal Regulation which state *exactly* what the law required in labeling about potential adverse reactions. In doing so, the Commissioner was monotonously consistent in putting the industry on notice that the duty to warn arose before a cause and effect relationship was established:

> "Indeed, from the beginning the legislation required warnings where the drug "may" be dangerous to health. It was nowhere suggested that there be proof of a health hazard before a warning could be required or that, absent such proof, any warning described varying opinions as to the degree of hazard involved. . . .
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> Warnings have been required on drug labels by the Food and Drug Administration **where there is significant medical evidence of a possible health hazard, *without waiting for a causal relationship to be established by definitive studies* which, in some instances, may not be feasible or would take many years. In this way, *physicians are fully apprised***

> ***of known potential dangers*, and the public more adequately protected . . . *drug warnings, by their very nature warn only about possible danger*** . . . debate and disagreement is properly the subject of scientific discussion in professional journals and symposia, but not in drug labeling. **As long as the statutory standard of *potential* danger is present, *the warning must be set it forth in clear, concise, and unambiguous terms*.** 39 FR 33231. (Emphasis added.)

Again, the Commissioner, commenting on the same sections on Monday, July 7, 1975, stated as follows:

> "The act provides that a food, drug, device, or cosmetic is misbranded if its labeling is false or misleading in any particular. The courts have uniformly held that a single misleading representation is sufficient to render a product misbranded. . . . The courts have also recognized that partial or half truths may render labeling misleading in violation of the act. . . .
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> The Commissioner has also noted that §201n of the act is not merely discretionary, since it provides that omissions of a material fact "shall" be considered in determining whether product labeling is misleading. . . . Commissioner concludes . . . the law requires labeling to include warnings about both potential and verified hazards. . . . Accordingly, labeling is not intended to be a dispositive treatise of all possible medical opinions about a drug. It is, instead, intended to advise about potential hazards and convey documented statements with respect to the safety and effectiveness. . . .
>
> Congress wisely concluded that potential hazards, as well as known hazards, should be included in labeling in order to warn physicians about possible adverse reactions. . . .
>
> Accordingly the Commissioner concludes that **drug labeling should include a warning *whenever reasonable evidence exists indicating an association***

between a drug and serious hazard. ***A causal relationship need not have been proved.*** . . .

* * * * *

A comment specifically objected to the Commissioner's conclusion that a clear and unambiguous warning must be included in labeling even though there is "serious medical and scientific doubt" about it. The comment contended that this position demeans the ability of physicians to digest and interpret material presented in drug labeling. It was suggested in the comment that an unqualified warning would likely be based upon more weighty evidence than "a mere suggestion" of a potential or danger unaccompanied by proof of a causal relationship.

The Commissioner reiterates that this comment is based upon a misunderstanding of the legal requirement for drug label warnings. **The statute requires that a warning be placed on the label *when there is a potential hazard, as well as when there is proof of a causal relationship* between the hazard and the drug. The congressional requirement of a clear drug warning under these circumstances assures that a potential hazard will be brought to the attention of the physician in straight forward and concise terms.**

* * *

The Commissioner advises that **where medical information justifies a warning, the law requires that the warning must be included in the drug labeling.** In accordance with the provision of the proposed new regulation governing prescription drug package inserts published in the Federal Register of July 7, 1975 (40 FR 15392), 'a warning shall be included in labeling as soon as there is reasonable evidence of an ***association*** of a serious hazard with a drug; ***a causal relationship need not have been proved.***" Federal Register, 40, No. 130, Monday, July 7, 1975, pages 28582-28584. (Emphasis added.)

Finally, on June 26, 1979, on the identical subject matter the Commissioner stated under Warnings:

> "Several comments contended that a definition of "reasonable evidence" associating a serious hazard with a drug is necessary, when a causal relationship has not been proved, to clarify when a serious hazard must be included in labeling . . .
>
> ***The Commissioner rejects these comments.*** A serious hazard must be included in the "Warnings" section of the labeling of a drug when evidence exists on the basis of which experts qualified by scientific training and experience can reasonably conclude that the hazard ***is associated with*** the use of the drug. ***A causal relationship need not be proved.*** . . .
>
> As stated above, the act and FDA regulations require a warning on a drug ***as soon as a hazard is associated with the use of the drug.*** In the case of a drug subject to an approved NDA, §314.8(d) (21 CFR 314.8(d) permits the addition of the drug's labeling or advertising of information about a hazard ***without advance approval of the supplemental application by FDA.*** . . .
>
> The statutory scheme for drug labeling requires that potential hazards, as well as known hazards, be included in labeling. Including conflicting opinions about such warnings would result in uncertainty and confusion and accordingly, decrease the usefulness of the warnings in protecting the public. FR, Volume 44, No. 124, Tuesday, June 26, 1979, pages 37447-37448. (Emphasis added.)

The interpretation of the Commissioner of Food and Drug Administration has the force of law. *Pharmaceutical Manufacturers v. Food and Drug Administration* (U.S.D.C. Delaware 1980) 484 Fed.Supp.1179, (affirmed 634 F.2d 106). In *Northern Trust Co. v. Louis A. Weiss Memorial Hospital* (1st Dist. 1986) 143 Ill.App.3rd 479, 493 N.E.2d

6, 13, the appellate court of the first district observed and held:

> "Our supreme court has stated that 'administrative rules and regulations have the force and effect of law, and must be construed under the same standards which govern the construction of statutes.' (*Northern Illinois Automobile Wreckers and Rebuilders Assn. v. Dixon* (1979), 75 Ill.2d 53, 58, 25 Ill.Dec. 664, 387 N.E.2d 320, *cert. denied* 444 U.S. 844, 100 S.Ct. 87, 62 L.Ed.2d 57.) Therefore, just as statutory interpretation presents a question of law, interpretation of the Board of Health's regulations is a question of law for the court to determine. *See Inwang v. Community College District No. 508, County of Cook* (1983), 117 Ill.App.3d 608, 611, 73 Ill.Dec.71, 453 N.E. 2d 896. . . .
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> * * *
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> The court must look first to the words of a regulation in order to determine its meaning. (*In re Marriage of Logston* (1984), 103 Ill.2d 266, 277, 82 Ill.Dec. 633, 469 N.E.2d 167.) The court properly determined that it was not bound by the testimony of witnesses regarding the meaning of the regulation. (*People ex rel. Brenza v. Gebbie* (1955), 5 Ill.2d 565, 577, 126 N.E.2d 657.)"

In *Feldman v. Lederle Laboratories* (Supreme Court of New Jersey, 1984) 97 N.J.429, 479 A.2d 374, plaintiff brought a product liability action against the drug manufacturer for failing to warn that tetracycline had the potential for discoloring tooth enamel. It was claimed there that the doctrine of strict liability in tort should not apply to prescription drugs. In that case, the defendant manufacturer contended that it complied with FDA regulations and somehow its compliance insulated it from any potential liability for failing to warn the plaintiff. The court noted, as courts in Illinois have previously noted,

that the manufacturer of ethical drugs is held to the standard of an expert, (497 A.2d 374, 386-387) and that

> "a manufacturer should keep abreast of scientific advances . . . (at 387) . . . Implicit in the requirement that such manufacturers held to the standard applicable to experts in the field is the notion that at least in some fields, such as those impacting on public health, a manufacturer may be expected to be informed and affirmatively to seek out information concerning the public's use of its own product."

The court goes on to cite 39FR 33230-331 (1974) for the proposition that the FDA requires warnings on drug labels "when there is significant medical evidence of a possible health hazard, without waiting for a causal relationship to be established by definitive studies which, in some instances may not be feasible or would take many years." In *Stanton v. Astropharmaceutical Products, Inc.* (CA 3rd Cir. 1983) 718 F.2d 553, a products liability action brought against a manufacturer as the result of an adverse reaction to a local anesthetic, the United States Court of Appeals for the Third Circuit reviewed the entire history of the federal regulatory scheme which emanates from Title 21 through the Code of Federal Regulations and the comments of the Commissioner (718 F.2d 553, 558-560) and held under Pennsylvania law the violation of a governmental safety regulation constitutes negligence *per se* if the regulation was in part intended to protect the interest of another, and the interest of the plaintiff which was invaded was one which the Act intended to protect. The court went on to hold that indeed the regulation of the labeling of ethical drugs and the statutory requirements was such a provision and the violation of those provisions was negligence *per se*, stating, 718 F.2d 553, 565,

> "Under Pennsylvania law, therefore, this case falls within §288B(1) of the Second Restatement: 'The unexcused violation of a legislative enactment or an administrative regulation which is adopted by the court as defining the standard of conduct of a reasonable man, is negligence in itself.' The jury therefore had sufficient evidence upon which to find that ASTRA had acted negligently in failing to file the reports required. . . ."

In conclusion, to hold that the plaintiff must produce "expert testimony," apparently in human form, to testify to the jury, completely ignores the traditional function of expert testimony in the law of Illinois. The expert is simply an aide to the trier of fact. By requiring "an expert" in order to prove a case against a drug manufacturer, the appellate court overlooks the fact that federal law governing the conduct of a drug manufacturer who markets drugs and formulates warnings is in fact the legal embodiment of the standard of care. While an expert witness might be required in a medical malpractice action to testify about the standard of care based on his knowledge and experience, in the case at bar, the plaintiff had an even more compelling source of information to enable the jury to try the factual issues of whether or not Upjohn complied with its duty to warn: the voice of the federal government, speaking through the Food and Drug Administration, which voice was articulated in those rules and regulations embodied in plaintiff's jury instruction No. 37. Expert testimony would not vary the mandatory nature of statutory regulation, which is far more concrete and far more probative and relevant to the duty of Upjohn to warn, than the testimony of some hired expert testifying on the basis of their own knowledge and experience. The Food and Drug Administration regulations are global and mandatory; they speak for themselves. The concept

that an expert witness is necessary to take the stand and translate those regulations to the jury, and that such an expert is the exclusive source by which a plaintiff may prove a case against a drug manufacturer is contrary to Illinois law, completely misapprehends the nature and purpose of expert testimony, *from whatever source*, and ignores completely the force and effect of federal law and the duty of the court, not an expert witness, to determine the meaning of laws.